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EXAMINER	
CHONG, KIMBERLY	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/652,791	MCSWIGGEN ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,38,51-59,68-72 and 75-78* is/are pending in the application.

4a) Of the above claim(s) *78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,38,51-59,68-72 and 75-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 12/26/2007 is acknowledged. Applicant has canceled claims 73 and 74, thereby making the restriction requirement moot.

Newly submitted claim 78 is withdrawn as being drawn to non-elected invention because it is directed to an invention that is independent or distinct from the elected invention for the following reasons: the composition comprising a chemically modified nucleic acid of the instant claims and the method of new claim 78 is drawn to inhibiting expression of human ECGF1 gene using said composition in claim 1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced using a material different product, such as a single stranded nucleic acid molecule. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 78 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Status of Application/Amendment/Claims

Applicant's response filed 12/26/2007 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 03/02/2007 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 12/26/2007, claims 36, 38, 51-59, 68-72 and 75-78 are pending in the application. Applicant has canceled claims 1-35, 37, 39-50, 60-67 and 75-78.

New Claim Objections and Rejections

The new ground of rejection is necessitated by the submission of new claims 70-72 and 75-77 in the amendment filed 12/26/2007.

Claims 70-72 and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyatt et al. (U.S. Patent No: 6,716,975 of record), Hammond et al. (Nature 2001 of record) and Tuschl et al. (WO 02/44321 of record).

Claims 70-72 and 75-77 of the instant application are drawn to chemically modified nucleic acid molecules comprising an antisense strand and a sense strand wherein each strand is 18 to 27 nucleotides in length and wherein the antisense strand if complementary to a nucleotide sequence of ECGF1 and wherein each stand comprises about 50 to about 100 percent of chemically modified nucleotides and

wherein the nucleic acid further comprises, 3' overhang regions, 1 to 10 or more phosphorothioate internucleotide linkages, 1 to 10 or more 2'-O-methoxyethyl nucleotides or 1 to 10 or more locked nucleic acids.

Wyatt et al. teach a nucleic acid molecule that is targeted to EDG1 (also known as ECGF1) (see column 3, lines 1-5 and Table 1) and comprises modified ribonucleotides or modified deoxyribonucleotides wherein the nucleic acid molecules are between 8-50 nucleotides in length and preferably 12-30 (see column 7, lines 35-58). Wyatt et al. further teach antisense compounds at least 19 nucleotides in length targeted to human EDG1 (see Table 1) and further teach at least 8 consecutive nucleobases of the antisense compound are complementary to the target gene (see column 6, lines 9-40). Wyatt et al. further teach the nucleic acid molecule comprises chemically modified nucleotides at the 3' or 5' end (see column 10, lines 47-57). Wyatt et al. further teach phosphorothioate internucleotide linkages (see column 8, lines 58-63) and further comprise 2'-O-methyl (see column 10, lines 35-50) and locked nucleic acid modifications (see column 11). Wyatt et al. do not teach a double-stranded nucleic acid molecule targeted to a EDG1 gene and further do not teach modified nucleotides comprising 2'-deoxy or 2'-deoxy-2'-fluoro.

Hammond et al. teach two methods for silencing specific genes: antisense and RNA interference. Hammond et al. teach that although antisense methods are straightforward techniques for probing gene function, the methods have suffered from "…questionable specificity and incomplete efficacy." (see page 110, column 1). Hammond et al. further teach " "…dsRNAs have been shown to inhibit gene expression

in a sequence-specific manner" and further "RNAi is a potent method, requiring only a few molecules of dsRNA per cell to silence expression." Hammond et al. do not teach double-stranded nucleic acid comprising nucleotide comprising 2'-deoxy or 2'-deoxy-2'-fluoro, or comprising two separate strands connected via a linker molecule.

Tuschl et al. teach siRNA molecules which are 21 nucleotides in length and wherein each separate strand comprises at least 19 nucleotides complementary to the nucleotides of the other strand (Figure 14). Tuschl et al. further teach substitutions on either strand by 2'deoxy residues or 2'-O-methyl residues and further teach at least two 3' terminal nucleotides which are not base-paired to the nucleotides of the other strand (see Figure 14). Tuschl et al. teach a 5'-phosphate on the antisense strand (see page 4, lines 12-20) and teach pharmaceutical compositions comprising double stranded nucleic acids and an acceptable carrier (see page 9, lines 17-25).

Parrish et al. teach dsRNA with an antisense or sense region comprising 2'-deoxy-2'-fluoro pyrimidine nucleotides (see Figure 5) and further teach this dsRNA can mediate degradation of cellular RNA (see abstract page 1082).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a dsRNA targeted to a human EDG1 gene, at taught by Wyatt et al. and further it would have been obvious for one of ordinary skill in the art to make a dsRNA which are 21 nucleotides in length with chemical modifications, as taught by Tuschl et al. and Parrish et al.

One would have been motivated to use a dsRNA targeted to a EDG1 gene instead of an antisense because Hammond et al. teach using dsRNA to inhibit gene

expression is more sequence specific than using antisense methodologies and RNAi using dsRNA is a more potent method requiring only a few molecules of dsRNA per cell. Further, Tuschl et al. and Parrish et al. provide motivation to make a dsRNA with chemical modifications because the length of the nucleotide and the modifications are important for mediating RNA interference. Moreover, Tuschl et al. clearly recognize that 2'-modifications enhance the nuclease stability of siRNA molecules and therefore one would have been motivated to search for particular chemical modifications that are tolerated by the siRNA by routine experimentation of determining the optimum number and placement of the 2'-modifications to see how well the modifications were tolerated with respect to stability and functionality of the siRNA. Further, because Tuschl et al. teach that modifying 8 of the 42 nucleotides with 2'-O-methyl provides a siRNA that efficiently mediates RNAi and teach that modifying 100% of the nucleotides with 2'-O-methyl nucleotides abolishes activity, one of skill in the art would have been motivated to incorporate various chemical modifications in various configurations to determine the optimum number and placements of such modifications.

Finally, one would have a reasonable expectation of success because Wyatt et al. teach antisense molecules can be targeted to a EDG1 gene and regulate gene expression, Hammond et al. teach that of the two methods used for silencing gene function, RNAi using dsRNA is more potent and sequence specific than antisense and finally Tuschl et al. and Parrish et al. teach making a dsRNA with chemical modifications is important for mediating RNAi. Further, one would have a reasonable expectation of success because chemical modifications of an oligonucleotide which have been shown

to add stability and specificity to oligonucleotides were known in the art at the time of the invention was made. Additionally, one would expect such modifications would benefit siRNAs because such modifications had been shown to benefit antisense or ribozymes.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Applicant's Arguments

Claim Rejections - 35 USC § 112

The rejection of claims 36, 38, 48-59 and 68-69 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to claim amendments filed 12/26/2007.

The rejection of claims 36, 38, 48-59 and 68-69 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicant's arguments.

The rejection of claims 54-55 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in response to claim amendments filed 12/26/2007.

Re: Double Patenting

Acknowledgement is made of Applicant's consideration of filing a terminal disclaimer upon allowance of the pending claims, therefore the rejection of claims 36, 38, 48-59 and 68-69 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 14-21, 30 and 35-36 of copending Application No. 10/922,034 is maintained.

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Re: Claim Rejections - 35 USC § 103

The rejection of claims 36, 38, 51-53, 56-59 and 68-69 under 35 U.S.C. 103(a) as being unpatentable over Wyatt et al. (U.S. Patent No: 6,716,975 of record), Hammond et al. (Nature 2001 of record), Tuschl et al. (WO 02/44321 of record), Parrish et al. (Molecular Cell, 2000 of record) and Cook et al. (U.S. Patent No. 5,587,471 of record) is maintained for the reasons of record filed 12/19/2005.

The rejection of claims 36, 38, 51-59 and 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyatt et al. (U.S. Patent No: 6,716,975 of record), Hammond et al. (Nature 2001 of record), Tuschl et al. (WO 02/44321 of record), Parrish et al. (Molecular Cell, 2000 of record) and in further view of Matulic-Adamic (U.S. Patent No. 5,998,203 of record) and Thomson et al. (Nucleic Acids Research 1993 of record) is maintained for the reasons of record filed 12/19/2005.

The rejection of record of claims 36, 38, 51-53, 56-59 and 68-69 under 35 U.S.C. 103(a) as being unpatentable over Meacci et al. (Biochem 2002 of record), Hammond et al. (Nature 2001 of record), Tuschl et al. (WO 02/44321 of record), Parrish et al.

(Molecular Cell, 2000) and Cook et al. (U.S. Patent No. 5,587,471 of record) is maintained for the reasons of record filed 05/19/2006.

Applicant's arguments are acknowledged but are not found persuasive. Applicant continues to assert that there was no reason for those skilled in the art to apply chemical modifications previously made on single stranded nucleic acid molecules to double stranded nucleic acid molecules. These arguments are simply not convincing.

It would have been obvious to one of skill in the art to incorporate known chemical modifications of inhibitory nucleic acid molecules into the siRNA taught by Tuschl et al. for the purpose of improving nuclease resistance and enhanced target specificity. At the time of filing of the instant application, the field was replete with prior art demonstrating predictable results of modifying inhibitory nucleic acid molecules for the purpose of increasing nuclease resistance and target specificity. Nucleic acid molecules, whether single or double stranded are equally susceptible to cellular nucleases and one of skill in the art would have wanted to incorporate known chemical modifications to increase the stability of said nucleic acid in cells. Therefore, because the instantly recited chemical modifications were known in the art to impart nuclease resistance and enhanced pharmacokinetics to inhibitory nucleic molecules that are used for the same purpose as the instantly claimed nucleic acid molecules, it would have been obvious to one of skill in the art to incorporate such modifications.

Applicant continues to argue that Wyatt et al. fails to teach double stranded nucleic acid or siRNA and fails to specifically teach targeting ECGF1. As stated in the previous response to Applicant's arguments, Wyatt et al. teach an antisense compound directed

to an endothelial differentiation gene (EDG1) wherein said antisense reduces expression of said target gene. Wyatt et al. teach such gene plays a role in angiogenesis and if uncontrolled, can lead to numerous pathologic conditions such as cancer (see column 1, line 66 to column 2, line 5). The specification lists the instantly claimed targets on page 136 and teach on page 6, lines 21-30 of the specification that targeting such ECGF1 genes with dsRNA are useful for modulation of angiogenesis and proliferation of cells such as in disorders such as cancer. While Wyatt et al. does not specifically recite targeting SEQ ID NO. 225, Wyatt et al. teach targeting a human EGF1, a gene having the same function as the instantly claimed gene, ECGF1. Therefore, one of skill in the art would have been motivated to target the instantly claimed SEQ ID No. 255 and further, one of skill in the would have clearly been motivated to substitute a siRNA for the antisense taught by Wyatt et al. for the modulation of target genes associated with angiogenesis and cell proliferation because siRNA has been shown to work more efficiently than antisense in inhibition of gene expression.

Regarding Tuschl et al., applicants continue to argue Tuschl et al. teaches away from the use of a 2'-O-methyl in siRNA either individually or in combination with a 2'deoxy-2'-fluoro modification. Applicants further continue to argue Tuschl et al. teach that 2'-O-methyl modifications cannot be used in a siRNA to mediate RNAi and further based on the teachings of Tuschl et al. one of skill in the art would not have been motivated to incorporate 2'-O-methyl modifications into siRNA molecules targeting ECGF1. As stated previously in response to Applicant's argument, Nowhere in the

disclosure of Tuschl et al. does it state or give the suggestion that 2'-O-methyl modifications cannot be used in a siRNA or that Tuschl et al. teach one of skill in the art should avoid 2'-O-methyl modifications, as asserted by Applicant. While it is true that Tuschl et al. teach away from extensive 2'-O-methyl modifications of one or both strands of the siRNA, one of skill in the art would have been motivated to incorporate 2'-O-methyl modifications from the disclosure in Tuschl et al. particularly given what was well known in the art at the time of the instant invention regarding the use of 2'-O-methyl modifications to impart duplex stability and nuclease resistance to oligonucleotides. Applicants have pointed to a section of Tuschl et al. (pages 49-50) for teaching that Tuschl et al. "flatly states that 2'-O-methyl modifications, as are presently claimed, should be avoided." (see remarks filed 08/25/2006 page 11-12). Applicant has based this statement on their interpretation of the sentence "More extensive 2'-deoxy or 2'-O-methyl modifications reduce the ability of siRNAs to mediate RNAi…" wherein the sentence means that the "more extensive" phrase in the sentence applies only to 2'-deoxy and not 2'-O-methyl in the sentence and therefore Tuschl et al. "flatly states" that 2'-O-methyl modifications of siRNA should be avoided. Tuschl et al. does not "flatly state" that one of skill in the art should avoid 2'-O-methyl modifications in siRNA. Tuschl et al. specifically teach in Figure 14 that siRNA with more extensive 2'-deoxy modifications on one or both strands or siRNA with more extensive 2'-O-methyl modifications one or both strands reduced the ability of the siRNAs to mediate RNAi. One of skill in the art would not interpret from those experiments in Figure 14 to mean that 2'-O-methyl would not be a useful modification of siRNA, particularly because it is

well known in the art the benefits of incorporating 2'-O-methyl modifications in any nucleic acid for increased stability and nuclease resistance. Further, contrary to Applicant's assertion that Tuschl et al. expressly teaches avoiding 2'-O-methyl modifications, Tuschl et al. is silent as the effects of modifying a siRNA with more than 8 of the 42 nucleotides with 2'-O-methyl and modifying less than 100% of the nucleotides with 2'-O-methyl nucleotides. Therefore, this observation would motivate the skilled artisan to incorporate various chemical modifications up to about 100% in various configurations to determine the optimum number and placements of such modifications.

Moreover, Tuschl et al. clearly recognize that 2'-modifications enhance the nuclease stability of siRNA molecules and therefore one would have been motivated to search for particular chemical modifications that are tolerated by the siRNA by routine experimentation of determining the optimum number and placement of the 2'-modifications to see how well the modifications were tolerated with respect to stability and functionality of the siRNA. Further, Applicant's assertion that the art teaches that any incorporation of 2'-O'methyl modifications "completely abolished RNAi" activity and "2'-O-methyl modifications should be avoided" and "2'-O-methyl modifications destroy RNAi activity" is baffling given what was known in the art about the benefits of incorporating such modifications into nucleic acid and particularly what was taught by Tuschl et al. as discussed above and throughout the previous office actions.

Applicants continue to argue Parrish et al. teach modifications of long siRNA and do not teach siRNA. As stated in the previous office actions, Parrish et al. was relied upon to impart stability and nucleic resistance to siRNAs given such modifications had

been shown in the art to benefit antisense and ribozymes. Applicant is correct in that Parrish et al. do not teach specifically teach short interfering RNA, however, the modifications taught by Parrish et al. provide stability to a dsRNA that are subsequently involved in RNAi and therefore one of skill in the art would have been motivated to incorporate said modifications into the siRNA taught by Tuschl et al. Moreover, one of skill would recognize that the long dsRNA molecules taught by Parrish et al. were necessarily cleaved into short interfering RNA molecules by Dicer. As such, Parrish supports Examiner's assertion that it was known in the prior art and obvious to test various chemical modifications of double stranded nucleic acid molecules to optimize the activity. Parrish et al. was relied upon solely to state that the nucleotide modifications were known in the art at the time of the instant invention and were known to impart specific benefits to dsRNA.

Response to Applicant's argument regarding Cook et al. are moot given Applicant has canceled claims drawn to the limitations for which Cook et al. was relied upon.

Applicants continued argument that modifications to ribozymes, as taught by Matulic Adamic et al. and Thompson et al., do not apply to modifications of siRNA are simply not convincing.

Both types of molecules, ribozymes and siRNA, are nucleic acids, a fact acknowledged by applicant (see remarks filed 05/19/2006, page 21) and one of skill in the art would have been motivated to incorporate terminal cap moieties to provide resistance and decrease degradation of said nucleic acid because each of these

modifications were known in the art to benefit nucleic acid technologies. Moreover, Applicants seem to agree with Examiner that the recognized chemical modifications of antisense and ribozyme art would be beneficial to double stranded nucleic acids as evidenced by the instant specification that discusses at length the previous applicable modifications of the prior art molecules of antisense and ribozymes.

Therefore, as discussed above, in the absence of evidence to the contrary, the invention, as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Kimberly Chong/
Examiner
Art Unit 1635